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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,136	07/18/2003	Jun Li	DD.1.0038.US2	5547
31629	7590	04/06/2006	EXAMINER	
OMEROS MEDICAL SYSTEMS, INC. 1420 FIFTH AVENUE SUITE 2675 SEATTLE, WA 98101			ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/624,136	<b>Applicant(s)</b> LI ET AL.	
	<b>Examiner</b> James W. Rogers	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-103 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, 17-23, 28-45, 57-69 drawn to a drug delivery system, comprising: a hydrogel formed from cyclodextrin and an amphiphilic copolymer, wherein the copolymer includes an A polymer block comprising a poly(alkylene oxide) and a B polymer block comprising a poly(hydroxyalkanoate); and a therapeutically amount of at least one therapeutic agent intimately contained within the hydrogel classified in class 524, subclass 68.
- II. Claims 12-16, 46-56, 70-82, 84-103 drawn to a drug delivery system, comprising: a hydrogel formed from cyclodextrin and an amphiphilic copolymer, wherein the copolymer includes an two A polymer block end segments comprising a poly(alkylene oxide) and a B polymer block mid-segment comprising a poly(hydroxyalkanoate); and a therapeutically amount of at least one therapeutic agent intimately contained within the hydrogel, classified in class 424, subclass 485.
- III. Claims 24-26, 83 drawn to a drug delivery system, comprising: a hydrogel formed from cyclodextrin and an amphiphilic copolymer, wherein the copolymer includes an A polymer block comprising a poly(alkylene oxide) and a B polymer block comprising a poly(hydroxyalkanoate); and a therapeutically amount of at least one therapeutic agent intimately contained within the hydrogel further comprising a secondary polymer

which complexes with/or conjugates the therapeutic agent intimately contained within the hydrogel, classified in class 514, subclass 772.3.

- IV. Claim 27 drawn to a drug delivery system, comprising: a hydrogel formed from cyclodextrin and an amphiphilic copolymer, wherein the copolymer includes an A polymer block comprising a poly(alkylene oxide) and a B polymer block comprising a poly(hydroxyalkanoate); and a therapeutically amount of at least one therapeutic agent intimately contained within the hydrogel further comprising DNA nanospheres, intimately contained within the hydrogel, classified in class 424, subclass 1.73.

Inventions I and II are directed to related in that they contain overlapping, but different components. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In this case, invention II is a amphiphilic triblock copolymer including a B polymer mid-segment and two A polymer block end segments not required in invention I.

Inventions I and III are directed to related in that they contain overlapping, but different components. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together

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or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In this case, invention III has an additional secondary polymer not required in invention I.

Inventions I and IV are directed to related in that they contain overlapping, but different components. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In this case, invention IV has an additional element not required in invention I a DNA nanophere.

Inventions II and III are directed to related in that they contain overlapping, but different components. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In this case, invention III has an additional secondary polymer not required in invention II and invention II is a amphiphilic triblock copolymer including a B polymer mid-segment and two A polymer block end segments not required in invention III.

Inventions II and IV are directed to related in that they contain overlapping, but different components. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not

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obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In this case, invention IV has an additional element not required in invention II a DNA nanosphere and invention II is a amphiphilic triblock copolymer including a B polymer mid-segment and two A polymer block end segments not required in invention IV.

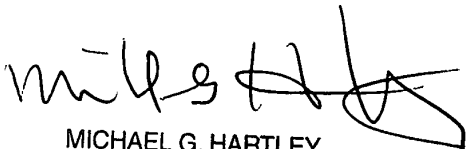
Inventions III and IV are directed to related in that they contain overlapping, but different components. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In this case, invention IV has an additional element not required in invention III, a DNA nanosphere and invention III has an additional secondary polymer not required in invention IV.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER